RECORD AND BRIEFS

(24)

FILED
AUG 27 2007
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 06-179

IN THE

Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

JOINT APPENDIX

ALLISON M. ZIEVE
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
(202) 588-7795 (fax)

Counsel of Record
for Petitioners

THEODORE OLSON
Gibson, Dunn & Crutcher
1050 Connecticut Avenue NW
Washington, DC 20036
(202) 955-8500
(202) 530-9575 (fax)

Counsel of Record
for Respondent

Petition for Certiorari Filed: August 3, 2006
Certiorari Granted: June 25, 2007

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

Docket No. 1:99-cv-00649-LEK-RFT

CHARLES R. RIEGEL AND DONNA S. RIEGEL, Plaintiffs,

v.

MEDTRONIC, INC., Defendant.

DOCKET ENTRIES

Filing Date	#	Docket Text
04/29/1999	1	COMPLAINT filed; FILING FEE $ 150.00 RECEIPT # 41768 ; Service deadline 6/28/99 for Medtronic, Inc. (wbl) (Entered: 04/30/1999)
04/29/1999		SUMMONS(ES) issued for Medtronic, Inc. (wbl) (Entered: 04/30/1999)
		* * * * *
06/09/1999	3	ANSWER to Complaint by Medtronic, Inc. (Attorney Richard Bakalor); jury trial demanded. (fce) (Entered: 06/09/1999)
06/18/1999	4	AMENDED ANSWER to Complaint by Medtronic, Inc. : amends [3-1] answer; jury demand (fce) (Entered: 06/18/1999)
		* * * * *

03/29/2000	17	Statement of Material Facts in Support of [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim filed by Medtronic, Inc. (tab) (Entered: 03/29/2000)
03/29/2000	18	AFFIDAVIT by Medtronic, Inc. Re: in support of [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 03/29/2000)
03/29/2000	19	MEMORANDUM by Medtronic, Inc. in support of [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 03/29/2000)
03/29/2000	20	Exhibits in support of defendant's motion for summary judgment and to dismiss claim. (tab) (Entered: 03/29/2000)

03/29/2000	21	Statement of Material Facts in Response to 's 6-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim filed by Charles R. Riegel, Donna S. Riegel (tab) (Entered: 03/29/2000)
03/29/2000	22	ANSWERING AFFIDAVIT by Wayne P. Smith as to Charles R. Riegel, Donna S. Riegel Re: in OPPOSITION to [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) Modified on 03/29/2000 (Entered: 03/29/2000)
03/29/2000	23	MEMORANDUM OF LAW by Charles R. Riegel, Donna S. Riegel in opposition to [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 03/29/2000)
03/29/2000	24	REPLY AFFIDAVIT by Medtronic, Inc. to response to [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 03/29/2000)

03/29/2000	25	REPLY Statement of Material Facts in Support of [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim filed by Medtronic, Inc. (tab) (Entered: 03/29/2000)
03/29/2000	26	REPLY MEMORANDUM by Medtronic, Inc. in further support of [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 03/29/2000)
		* * * * *
05/23/2000	29	SUR-REPLY RESPONSE by Charles R. Riegel, Donna S. Riegel Reply Memorandum to [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 05/23/2000)
		* * * * *

03/18/2002	33	MEMORANDUM-DECISION AND ORDER granting in part, denying in part [16-1] motion for Summary Judgment and/or Partial Summary Judgment, denying [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (signed by Judge Lawrence E. Kahn) Date Entered: 3/18/02 (tab) (Entered: 03/18/2002)
		* * * * *
05/23/200[3]	50	AFFIDAVIT by Ted Milo as to Charles R. Riegel, Donna S. Riegel Re: in opposition to [47-1] motion for Summary Judgment (tab) (Entered: 05/27/2003)
		* * * * *
12/11/2003	60	Memorandum-Decision and ORDER granting [47] Motion for Summary Judgment and Dismissing action. Signed by Judge Lawrence E. Kahn on 12/2/03. (tab,) (Entered: 12/16/2003)
12/11/2003	61	JUDGMENT in favor of Defendants against Plaintiffs (tab,) (Entered: 12/16/2003)

01/08/2004	62	NOTICE OF APPEAL as to [60] Order on Motion for Summary Judgment, [61] Judgment by Charles R. Riegel, Donna S. Riegel. Filing fee $ 255, receipt number 70951. (jel,) (Entered: 01/09/2004)

* * * * *

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Docket No. 04-0412-cv

CHARLES R. RIEGEL AND DONNA S. RIEGEL,
Plaintiffs-Appellants,

v.

MEDTRONIC, INC., Defendant-Appellee.

DOCKET ENTRIES

1/22/04	Copy of notice of appeal and district court docket entries on behalf of APPELLANT'S Charles Riegel and- Donna Riegel, filed. Forms C and D due on 1/24/04. [Entry date Feb 4 2004] [TM]

* * * * *

3/8/05	APPELLANTS Charles Riegel and Donna Riegel, brief FILED with proof of service. [Entry date Mar 31 2005] [TM]
3/8/05	APPELLANTS Charles Riegel and Donna Riegel, appendix filed w/pfs.(three volumes) [Entry date Mar 31 2005] [TM]
3/8/05	APPELLANTS Charles Riegel and Donna Riegel, special appendix filed (w/pfs) [Entry date Mar 31 2005] [TM]

* * * * *

5/10/05	APPELLEE Medtronic, Inc., brief with Addendum, filed with proof of service. [Entry date May 11 2005] [TM]
5/18/05	AMICUS CURIAE Product Liability Advisory Council, brief filed with proof of service. [Entry date May 26 2005] [TM]
5/27/05	APPELLANTS Charles Riegel and Donna Riegel,

	reply brief filed with proof of service. [Entry date Jun 7 2005] [TM]
	* * * * *
12/15/05	Case heard before POOLER, KATZMANN, PARKER, C.JJ. CD dated: December 15, 2005. [Entry date Dec 15 2005] [AG]
5/9/06	APPELLEE Medtronic, Inc., 28(J) letter received. [Entry date May 10 2006] [TM]
	* * * * *
5/16/06	Judgment of the district court is AFFIRMED by published signed opinion filed. (RAK) [Entry date May 16 2006] [TM]
5/16/06	Judge POOLER dissents in a separate opinion, filed. [Entry date May 16 2006] [TM]
5/16/06	Judgment filed. [Entry date May 16 2006] [TM]
	* * * * *
6/6/06	Judgment MANDATE ISSUED. CLOSED [Entry date Jun 6 2006] [TM]
	* * * * *
8/1/06	Errata sheet re: filed. [Entry date Aug 2 2006] [TM]
	* * * * *
7/2/07	Letter dated 6-25-07 from the Supreme Court advising of order GRANTING petition for writ of certiorari by APPELLANTS Charles Riegel and Donna Riegel, , filed. (Supreme Court # 06-179) [Entry date Jul 5 2007] [TM]
7/2/07	Writ of Certiorari GRANTED. [Entry date Jul 5 2007] [TM]

Exhibits to Affidavit of James Shy in Support of Defendant's Motion for Summary Judgment, United States District Court for the Northern District of New York, No. 99-CV-0649, dated January 26, 2000, and filed March 29, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

MAR 25 1988

Ronald J. Solar, Ph.D.
Vice President and Technical Director
Versaflex Delivery Systems, Inc.
4060 Sorrento Valley Blvd.
San Diego, California 92121

Re: P870036
Versaflex™ Buchbinder™ Omniflex™ PTCA Catheter System
Filed: June 16, 1987
Amended: October 23, 1987 and January 22, 1988

Dear Dr. Solar:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Versaflex™ Buchbinder™ Omniflex™ PTCA Catheter System. This device is indicated in patients with coronary artery disease who are acceptable candidates for coronary artery bypass graft surgery, in addition to meeting one or more of the following criteria listed below:

1. Single-vessel atherosclerotic coronary artery disease that is concentric, discrete, subtotal, noncalcified, and accessible to a dilatation catheter.

2. Multiple-vessel coronary artery disease under certain circumstances.

3. Coronary artery disease of the native coronary arteries

and/or coronary artery bypass grafts of some patients who have previously undergone coronary artery bypass graft surgery, have recurrence of symptoms, and (a) progression of disease, or (b) stenosis and closure of the grafts.

The PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter. Expiration dating for this device has been established and approved at 6 months.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (act) under authority of section 515(d)(1)(B)(ii) of the act.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. In addition, the notice will state that a copy of all approved labeling (which may be a draft of the final labeling) is available for public inspection at the CDRH. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

All required documents must be submitted in triplicate, unless otherwise specified, to the address below and shall reference the

above PMA number to expedite processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have any questions concerning this approval order, please contact Ms. Nadine Y. Rosile, at (301) 427-7371.

Sincerely yours,

/s/
Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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REVISED: November 19, 1986

CONDITIONS OF APPROVAL

Approved Labeling. As soon as possible, and before commercial distribution of your device, submit two copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the Food and Drug Administration (FDA), Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Advertisement. No advertisement and other descriptive printed material issued by the application or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If FDA has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

Premarket Approval Application (PMA) Supplement. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or for which FDA has advised in an advisory opinion or in correspondence in accordance with 21 CFR 814.39(e) that an alternate submission is permitted. A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices (51 FR 26342) published in the Federal Register of July 22, 1986.

Postapproval Reports. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the Food and Drug Administration, Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) Published reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two

copies of each identified report when so notified by FDA.

Adverse Reaction and Device Defect Reporting. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified as an "Adverse Reaction Report" or "Device Defect Report", as applicable, to the Food and Drug Administration, Center for Devices and Radiological Health, 8757 Georgia Avenue, Silver Spring, Maryland 20910 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occuring [sic] with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the

Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

AUG 30 1994

Mr. Timothy J. Johnson [date stamp omitted in printing]
Regulatory Affairs Manager
Medtronic Interventional Vascular
9410 Carroll Park Drive
San Diego, California 92121-2256

Re: P870036/S30
Medtronic® Evergreen™ PTCA Catheters
Filed: March 9, 1994
Amended: April 11 and August 18, 1994

Dear Mr. Johnson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for a new model of PTCA Catheter. The devices will be marketed under the trade name Medtronic® Evergreen™ PTCA Catheters and are indicated for PTCA. Based upon the information submitted, the PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device as modified by your PMA supplement upon receipt of this letter.

Failure to comply with the conditions of approval as attached invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Glenn N. Byrd at (301) 594-2726.

Sincerely yours,

/s/
Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 1995

Mr. Kenneth Keown
Senior Regulatory Specialist
Medtronic Interventional Vascular
9410 Carroll Park Drive
San Diego, California 92121-2256

Re: P870036/S35
Versaflex™ Buchbinder™ Omniflex™ PTCA Catheter System
Medtronic® 18K®, 14K®, Evergreen™, Falcon™, Panther™, and Spirit® PTCA Catheters
Filed: April 7, 1995

Dear Mr. Keown:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for revised labeling. Based upon the information submitted, the PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device as modified by your PMA supplement upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must

not violate sections 502(q) and (r) of the act.

Failure to comply with the conditions of approval as attached invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Glenn N. Byrd at (301) 443-8243.

Sincerely yours,

/s/
Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

[date stamp omitted in printing]

Issued: 10-7-94

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the application or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgement by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgement is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test

results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance

procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you

shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-544)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 3083
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the above address or by telephoning (301) 594-2735.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 [year illegible]

Ms. Kathleen T. Boehm
Regulatory Affairs Specialist
Medtronic Interventional Vascular
9410 Carroll Park Drive
San Diego, California 92121-2256

Re: P870036/S32
Versaflex™ Buchbinder™ Omniflex™ PTCA Catheter System
Medtronic® Evergreen™ 40 Coronary Balloon Dilatation Catheter
Filed: October 17, 1994

Dear Ms. Boehm:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for: (1) a 40 mm long balloon version of the Evergreen™ PTCA catheter which incorporates an alternate strain relief assembly; and (2) an alternate strain relief assembly for use on the Evergreen™ and the Evergreen™ 30 PTCA Catheters. Based upon the information submitted, the PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device as modified by your PMA supplement upon receipt of this letter.

The sale, distribution, and use of this device are restricted to

prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Failure to comply with the conditions of approval as attached invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Glenn N. Byrd at (301) 443-8243.

Sincerely yours,

/s/
Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

[date stamps omitted in printing]

Issued: 10-7-94

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the application or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgement by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgement is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test

results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA

concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance

procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you

shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-544)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 3083
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the above address or by telephoning (301) 594-2735.